ORAL HEALTH PREPARATION AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to a method and composition for prevention and treatment of gingivitis and periodontitis, as well as dental caries. More particularly, the present invention relates to the use of phosphates in conjunction with stabilized chlorine dioxide to provide a mouth rinse or nonsudsing detergent toothpaste having increased stability and shelf life at a pH which maintains the effectiveness of stabilized chlorine dioxide in reducing the motility of and in killing bacterial pathogens.

2. Description of the Prior Art

The volatile sulfur compounds, hydrogen sulfide (H_2S) methylmercaptan (CH_3SH) and di-methylmercaptan $(CH_3)_2S$ are recognized in the current dental literature as being the major contributors to oral malodor. Numerous researchers using organoleptic, chemical, amperometric, mass spectrometric, gas or liquid chromatographic methods have demonstrated that these volatile sulfur compounds are present in the head space and vapor of putrefied saliva and in individual samples of mouth air. In most persons, hydrogen sulfide and methylmercaptan constitute over 90% of the total volatile sulfur content identified in mouth air. Further, the sulfur compounds increase the ability of bacteria and their toxic byproducts to penetrate the lining epethelial barrier of oral mucosa and penetrate into the underlying connective tissue. (Gaffer and Rizzo papers referenced in "Effect of Hydrogen Sulfide and Methyl Mercaptan on the Permeability of Oral Mucosa," J. Dent Res. 63(7), Jul. 1984, pages 994–997).

These malodorous volatile sulfur compounds are generated primarily through the putrefication action of oral microorganisms on sulfur containing amino acids, peptones or proteins found in the mouth. These substrates are readily available in saliva and dental plaque or may be derived from proteinaceous food particles trapped between the teeth, in the gingival crevices or adhering to the mucous membranes and the irregular surface of the tongue as well as exfoliated oral epithelium food debris and the like. Current studies have indicated that mouth odor not only comes from the posterior dorsal surface of the tongue but also from periodontal pockets. People with periodontal involvement have an attendant increase in oral malodor from disintegrated epithelial cells.

Starting with a clean tooth surface, plaque formation and resulting ecology occurs in the following steps:

1. Deposition of a coating of glycoproteins from salivary and other oral mucous gland secretions. This is referred to as acquired pellicle.

2. Fastening and colonization of streptococcus organisms to the acquired pellicle primarily by streptococcus sanguis and streptococcus mutans.

3. Conversion of sucrose to glucans (dextran) and fructans by the bacterial enzyme glucosyltransferases. In this plaque mass are imbedded dead cells, cell debris and food debris. High molecular weight polymers of glucose and other sugars, altered salivary glycoproteins, proteases and various chemotactic and inflammatory inducing substances have been detected and partially characterized.

4. Other organisms, primarily gram positive aerobes, become residents in the plaque mass and use the glucans and fructans for nutrition. These are primarily oxygen using organisms and the oxygen source is from the saliva that bathes the plaque mass.

5. With time and the functioning of this ecological system, the oxygen use by the superficial bacteria deprive the lower layers of the plaque matrix of a supply of oxygen. An opportunity is provided for non-oxygen using bacteria (facultative anaerobes) to become established.

6. If left undisturbed, the ecological system now established is self perpetuating. That is, the streptococcus bacteria continue to produce glucans and fructans. Other bacteria product produce toxins that kill cells of the host and the dead cells become other essential nutrients. The superficial bacteria deprive the deeper layers of the plaque mass of oxygen and keep the ecological system going. Thus, both aerobic and anaerobic organisms survive in the plaque mass.

7. The established ecological system attendant the plaque mass produces toxins from the aerobic bacteria that cause gingivitis and toxins from an aerobic bacteria that cause periodontitis.

Various substances have been tested for their ability to disrupt plaque or prevent its formation and to treat mouth odor such as antibiotics, chlorhexidines, oxine, and alexidine.

Over the years, mouth washes and toothpastes have been supplemented with additives which claim to have beneficial effects against dental diseases. For example, fluoride added to toothpaste has been shown to reduce dental caries but has not been shown to prevent gingivitis and periodontal disease. As described in U.S. Pat. No. 4,198,394, the effectiveness of fluoride is reportedly enhanced by adding sodium dihydrogen phosphate to the fluoride containing dentifrice. Phosphate compounds have also been used to stabilize dentifrices, as described in U.S. Pat. No. 3,622,662 (dental creams) and U.S. Pat. No. 3,577,521 (toothpastes). The prior art compositions that have been used and tested have found some acceptance but are generally ineffective in periodontitis, gingivitis, plaque accumulation and mouth malodor. On the other hand, U.S. Pat. Nos. 4,689,215 and 4,818,519 describe the use of stabilized chlorine dioxide in aqueous solution for the treatment of the mouth as a deodorizing agent, antiplaque agent, bactericide for treatment of gingivitis and periodontitis and as a bactericidal fungicidal and viralcidal agent in other related applications.

Stabilized chlorine dioxide and a method of making it are described in U.S. Pat. No. 3,271,242; stabilized chlorine dioxide is sold by Bio-Cide International, P.O. Box 2700, Norman, Okla., 73070 under the name Purogene. Further discussion of stabilized chlorine dioxide may be found in a treatise entitled "Chlorine Dioxide" by W. J. Masschelein and published by the Ann Arbor Science Publishes, Inc., copyright 1979 (note in particular pages 138–140). Various embodiments of chlorine dioxide for various purposes are also reviewed in this treatise.

Chlorine dioxide, ClO_2, functions biochemically in many ways other than as a germicide. These functions include: (1) oxidation of double bonds between two carbon atoms; (2) oxidation of unsaturated fatty acids (lipids) via double bonds between two carbon atoms; (3) acceleration of hydrolysis of carboxalic anhydrides: (4) oxidation of aldehydes to the corresponding carboxylic acids; (5) oxidation of alcohols; (6) oxidation of amines; (7) oxidation of phenols, phenolic derivatives and thi-